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10/521,176	01/14/2005	Hiroshi Okamura	OKAMURA6	2935

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EXAMINER	
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1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,176	OKAMURA ET AL.	
	Examiner	Art Unit	
	NARAYAN K. BHAT	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 December 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17,19-21 and 31-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17,19-21 and 31-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

FINAL ACTION

1. This office action is written in response to the papers filed on December 16, 2010. The amendments requiring the new limitation of a surface treated layer comprising diamond between the substrate and the electrostatic layer in instant claim 17 necessitated the new grounds of rejection presented in this office action. Accordingly, ***this action is made final.***

Claim Status

2. Claims 17, 19-21 and 31-35 are pending in this application and are under prosecution. Claim 17 is amended and new claims 33-35 are added. Claim amendments have been reviewed and entered. Applicant's arguments filed on December 16, 2010 have been fully considered and addressed following rejections.

The previous rejection of claims 17, 19, 20 and 31 under 35 USC 103 (a) as being unpatentable over Mao et al in view of Mirus et al in the office action dated August 17, 2010 has been withdrawn in view of the claim amendments. The previous rejection of claim 32 under 35 USC 103 (a) as being unpatentable over Mao et al in view of Mirus et al and further in view of Bertrand et al in the office action dated August 17, 2010 has been withdrawn in view of the claim amendments. The previous rejection of claims 17, 19, 20, 31 and 32 under 35 USC 103 (a) as being unpatentable over White in view of Mirus et al or Mirus et al in view of White in the office action dated August 17, 2010 has been withdrawn in view of the claim amendments. The previous rejection of claim 21 under 35 USC 103 (a) as being unpatentable over White in view of Mirus et al further in

view of Woo et al in the office action dated August 17, 2010 has been withdrawn in view of the claim amendments.

Priority

3. Applicant has submitted the certified English translation of the priority document JP 2002-207866 (filed on July 7, 2002) and JP2002-275797 (filed on September 20, 2002) in the copending divisional application 12/246,152. Applicant states that when the priority documents were translated from the Japanese, "polyallylamine" was mistranslated as "polyarylamine" (Remarks, November, 12, 2009, pg. 16). Applicant has submitted the non-certified English translation of the said priority documents on May 14, 2009 in the instant application and has support for the claimed “polyarylamine” but not for polyallylamine. Since the certified English translations of the priority documents in the instant application have not been received, Applicant is requested to clarify the discrepancies between the non-certified English translation of the priority documents submitted in the instant application versus the certified English translation submitted in the copending divisional ‘152 application. Since Applicant neither provided the requested information nor clarified the said discrepancy between two translations, the priority date for the instant application is July 3, 2003.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 32, 34 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The following rejection is necessitated by the claim amendments.

6. Claims 32 and 35 recite the limitation "the thickness" in line 2. There is insufficient antecedent basis for "the" thickness in the said instant claims and in claim 17 from which they depend from. Applicant is suggested provide proper antecedent basis for the limitation "the" thickness.

7. Claim 34 recites the limitation of "a nucleic acid is covalently bound to the carboxyl group in line 2." There is insufficient antecedent basis for "the" carboxyl group in the said instant claim and in claim 17 from which they depend from because claim 17 does not set forth a carboxyl group on the chemically modifying layer for covalently binding to a nucleic acid molecule. Applicant is suggested provide proper antecedent basis for the limitation "the" carboxyl group.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the

various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 17, 19-20 and 31-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al (USPGPUB 2003/0008413 published Jan. 9, 2003) in view of Mirus et al (WO 01/02538 published Jan. 11, 2001).

The following rejection is necessitated by the claim amendments.

The solid support of instant claim 17 recites the following structural components: a) a substrate, b) a positively charged electrostatic layer on the substrate, c) a surface treated layer comprising diamond between the substrate and the electrostatic layer, d) a chemically modifying layer containing a carboxyl group on the electrostatic layer and e) a nucleic acid molecule covalently bonded to the chemically modifying layer.

Kim et al teaches a solid support for manufacture of nucleic acid microarrays (paragraph 007) and Mirus et al also teaches a solid support for manufacture of nucleic acid microarrays (pg. 3, lines 29-31).

Regarding claim 17, Kim et al teaches the structural components ‘a’ to ‘d’ as illustrated in Fig. 2 and as discussed below. Mirus teaches the structural component ‘e’ as discussed below.

Regarding structural component 'a', Kim et al teaches a substrate 10 (Fig. 2A, paragraph 0075).

Regarding structural component 'b', Kim et al teaches providing a polyelectrolyte layer 14 comprising a polyamine compound (Fig. 2A, paragraph 0075). The instant specification recites that electrostatic layer comprises positively charged compound such as amino group containing compound (USPGPUB, paragraph 0040). The polyelectrolyte layer comprising polyamine compound layer on the substrate of Kim et al is the electrostatic layer as recited in the instant specification.

Regarding structural component 'c', Kim et al teaches that the substrate surface comprises a layer of diamond like carbon upon which polyelectrolyte layer is formed (paragraphs 0057-0058), thus teaching a diamond like carbon layer between the substrate and the electrostatic layer (i.e., the polyelectrolyte layer). The diamond like carbon of Kim et al is the diamond as recited in instant claim 33.

Regarding structural component 'd', Kim et al teaches providing a layer of a tri-alkoxysilyl cyclic anhydride layer 16 containing a carboxyl group on the polyelectrolyte layer 14 (Fig. 2B or 2C and paragraphs 0076-0079) and further teaches that the anhydride portion reacts with the amine groups of the electrostatic layer (i.e., the polyelectrolyte layer 14) converting the amine groups to an un-protonatable species (Fig. 2C and paragraphs 0076-0079), thus teaching a chemically modifying layer containing a carboxyl group on the electrostatic layer (i.e., the polyelectrolyte layer). The carboxyl group of Kim et al is the functional group for covalently binding to a nucleic acid molecule as recited in instant claim 34.

Regarding structural component ‘e’, Kim et al teaches that the polyelectrolyte coated substrates are suitable fabrication of biomolecular array and further teaches that the nucleic acid molecule is bonded to the substrate (Abstract, paragraphs 0007, 0080 and 0086). Kim et al do not explicitly teach a DNA molecule covalently bound to the chemically modifying layer.

FIG.2A

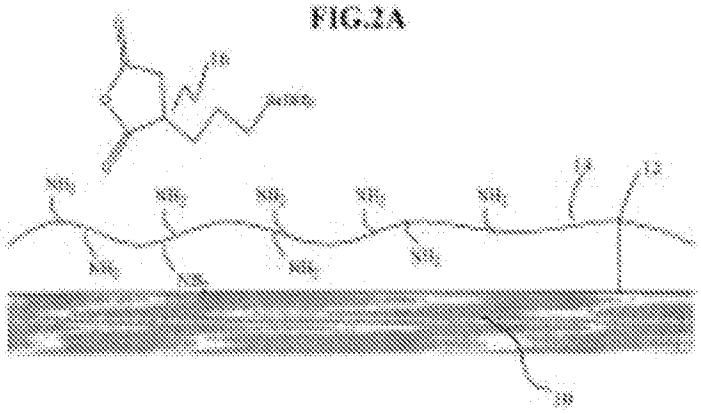


FIG.2B

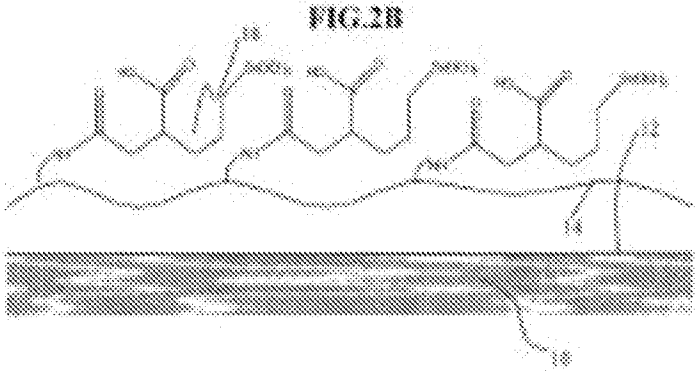
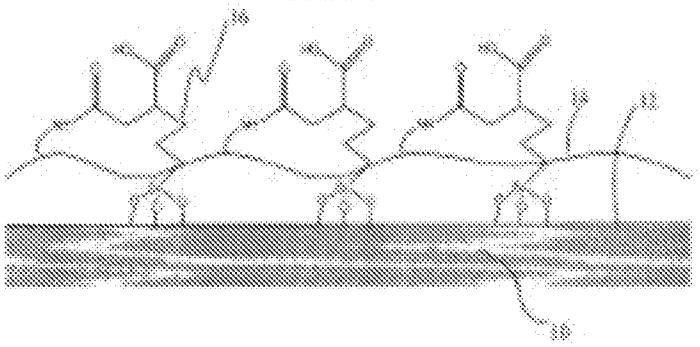


FIG.2C



Regarding claim 19, Kim et al teaches that the polyelectrolyte layer (i.e., the electrostatic layer) comprises the polyamine compound, which includes an amino group that does not bind to the substrate covalently (Fig. 2A).

Regarding claim 20, Kim et al teaches that the polyelectrolyte layer (i.e., the electrostatic layer) includes a polyamine compound having an amino group and covalently binds to the substrate via alkoxysilyl cyclic anhydride (Fig. 2C) and further teaches controlling the reaction for formation of covalent bonds (paragraph 0077). One of skill in the art would recognize that some of the amino groups of the polyelectrolyte layer of Kim et al remain free in a controlled reaction, which encompasses the polyamine compound containing amino groups has an amino group at the terminus to which the substrate does not bind.

Regarding claim 31, Kim et al teaches that the nucleic acid molecules are immobilized on the solid support as a spot (paragraphs 0080-0081).

Regarding claim 32, Kim et al teaches that the thickness of the polyelectrolyte layer (i.e., the electrostatic layer) is about 500 nm (paragraph 0031), which is in the range of 1 nm to 500 microns.

Regarding claim 33, Kim et al teaches diamond like carbon (paragraph 0057).

Regarding claim 34, Kim et al teaches carboxyl groups on the polyelectrolyte layer 14 (Fig. 2B) and binding of nucleic acid (paragraph 0080 an d0086). Kim et al do not teach explicitly that the nucleic acid is covalently bound to the carboxyl group.

Regarding claim 35, Kim et al teaches that the thickness of the surface treated layer (i.e., the diamond like layer) is about 100 nm (paragraph 0057), which is in the range of 1 nm to 100 nm.

As described above, Kim et al do not explicitly teach a nucleic acid molecule bonded covalently to the chemically modifying layer. However, a nucleic acid molecule bonded covalently to the chemically modifying layer was known in the art at the time the claimed invention was made as taught by Mirus et al.

Like Kim et al, Mirus et al teaches a solid support for nucleic acid immobilization comprising a substrate (pg. 5, line 3) further comprising a 3-aminopropyltriethoxysilane, which provides a surface with functional groups capable of reacting with a polyanion compound (pg. 5, lines 3-15). The silane compound on the substrate surface of Mirus et al encompasses a layer. Mirus et al also teaches that the substrate surface comprising silane compound reacts with the polyanion compound and further teaches that the polyanion compound is polyacrylic acids having a carboxyl functional group capable of covalently binding to a nucleic acid (pg. 3, lines 3-10). The polyacrylic acids reacting with silane compound on the substrate surface of Mirus et al encompasses a chemically modifying layer on the silane layer. Mirus et al also teaches that the nucleic acid molecule bonded covalently to the carboxyl functional group of polyacrylic acid (i.e., a chemically modifying layer; pg. 3, lines 7-10). Mirus et al further teaches that the nucleic acid molecule is immobilized as a spot (pg. 10, lines 3 and 29-30).

Mirus et al also teaches that the covalent binding of nucleic acids to the substrate increases the concentration of the nucleic acids irrespective of their size on the support, thereby enhancing the sensitivity of target detection (Tables 1-4, pg. 15, lines 9-13).

As described above, Both Kim et al and Mirus et al teach that the substrate comprises a glass substrate (Kim et al, paragraph 0056; Mirus et al pg.3, lines11-12). Kim et al also teaches that the substrate further comprises a diamond layer, a polyamine layer (i.e., an electrostatic layer), a layer of a tri-alkoxysilyl cyclic anhydride layer 16 containing a carboxyl group on the polyelectrolyte layer 14 and the polyelectrolyte layer is suitable for the manufacture of nucleic acid microarray (Abstract, paragraphs 0007, 0080 and 0081). Mirus et al teaches that the substrate comprises a layer of silane and a layer of polyacrylic acid containing carboxyl functional groups (i.e., a chemically modified layer) for covalent binding of the nucleic acid molecule and the substrate is suitable for preparing nucleic acid microarray (pg. 2, lines 29-31). Furthermore, the chemically modifying layer of Kim et al and Mirus et al comprise carboxyl groups for covalent bonding of nucleic acids to the substrate. Therefore the prior art of Kim et al and Mirus et al are analogous art and one of ordinary skill in the art would recognize that they are combinable to arrive at the claimed solid support.

Thus the combined teachings of Kim et al in view of Mirus et al meet the limitations of the structural components of instant claim 17, because, as described above the structural components of the solid support not taught by Kim et al are taught by Mirus et al.

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the nucleic acid immobilization to the substrate of Kim et al with the covalent attachment of nucleic acid with the substrate of Mirus et al with a reasonable expectation of success with the expected benefit of covalent binding of nucleic acids to the substrate thereby increasing the concentration of the nucleic acids irrespective of their size on the support, thereby enhancing the sensitivity of target detection as taught by Mirus et al (Tables 1-4, pg. 15, lines 9-13). An artisan having ordinary skill in the art would have a reasonable expectation of success because it merely involves covalent coupling of nucleic acids to the carboxyl functional groups on the surface, which also is routinely practiced in the art as exemplified by Mirus et al. Furthermore, the solid supports of both Kim et al and Mirus et al are drawn to immobilizing nucleic acids in the microarray format. Therefore, the claimed solid support is obvious over Kim et al and Mirus et al because they teach the structural components of the claimed solid support (MPEP 2114).

11. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al (USPGPUB 2003/0008413 published Jan. 9, 2003) in view of Mirus et al (WO 01/02538 published Jan. 11, 2001) as applied to claims 17 and 19 as above and further in view of Woo et al (USPN 5,929,194 issued July 27, 1999).

The following rejection is necessitated by the claim amendments.

Claim 21 is dependent from claim 19, which is dependent from claim 17. The teachings of Kim et al and Mirus et al regarding claims 17 and 19 are described above in section 10.

Regarding claim 21, Kim et al teaches a variety of amino groups containing compounds (paragraph 0061). Mirus et al teaches substrate comprising amino groups and further teaches that they are commercially available (pgs. 8 and 9). Kim et al and Mirus et al do not teach the amino group containing compound polyarylamine. However, the amino group containing compound polyarylamine was known in the art at the time the claimed invention was made as taught by Woo et al.

Woo et al teaches a polyarylamine compound for coating the glass substrate and forming films on the substrate carrying positive charges (column 1, line 60 and column 4, lines 8-10). Woo et al further teaches that the coating with the polyarylamine makes the substrate solvent resistant (column 4, lines 10-11, column 14, lines 13-17).

It would have been prima facie obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the amino group containing compound of Kim et al with the polyarylamine compound of Woo et al with a reasonable expectation of success with the expected benefit of having the polyarylamine compound for coating the substrate for making the substrate solvent resistant as taught by Woo et al (column 14, lines 13-17). An artisan having ordinary skill in the art would have a reasonable expectation of success because it merely involves substituting one amino group containing compound with the other, which also is routinely practiced in the art as exemplified by Kim et al and Woo et al.

Response to Remarks from the Applicant

Claim rejections under 35 U.S.C. § 103(a)

12. Applicant's arguments filed December 16, 2010 with respect to claims 17, 19, 20 and 31 rejected under 35 USC 103 (a) as being unpatentable over Mao et al in view of Mirus et al have been fully considered (Remarks, pg. 6) and are moot in view of the withdrawn rejection necessitated by claim amendments.

Applicant's arguments with respect to the teachings of Mirus et al as it pertains to the rejections made in this office action are directed to Mirus et al not teaching or suggesting a surface treated layer comprising diamond between the substrate and the electrostatic layer (Remarks, pg. 6). The Examiner acknowledges that Mirus et al do not teach the diamond layer. However, as described above in section 10, the diamond layer between the substrate and the electrostatic layer is taught by Kim et al.

Applicant's arguments with respect to claim 21 rejected under 35 USC 103 (a) as being unpatentable over Mao et al, Mirus et al and Woo et al have been fully considered (Remarks, pg. 6) and are moot in view of the withdrawn rejection necessitated by claim amendments.

Applicant's arguments with respect to teachings of Woo et al as it pertains to the rejections made in this office action are directed to Woo et al not teaching or suggesting a surface treated layer comprising diamond (Remarks, pg. 6). The Examiner acknowledges that Woo et al do not teach the diamond layer. However, as described

above in section 10, the diamond layer between the substrate and the electrostatic layer is taught by Kim et al.

Applicant's arguments with respect to claim 32 rejected under 35 USC 103 (a) as being unpatentable over Mao et al, Mirus et al and Bertrand et al have been fully considered (Remarks, pg. 7) and are moot in view of the withdrawn rejections necessitated by claim amendments.

Applicant's arguments with respect to claims 17, 19, 20, 31 and 32 rejected under 35 USC 103(a) as being unpatentable over White in view of Mirus et al or alternatively Mirus et al in view of White have been fully considered (Remarks, pg. 7) and are moot in view of the withdrawn rejections necessitated by claim amendments.

Applicant's arguments with respect to teachings of Mirus et al and Woo et al as it pertains to the rejection made in this office action have been addressed above.

Conclusion

13. No claims are allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH

shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Narayan K. Bhat whose telephone number is (571)-272-5540. The examiner can normally be reached on 8.30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571)-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Narayan K. Bhat/

Examiner, Art Unit 1634

/Steven C Pohnert/

Primary Examiner, Art Unit 1634